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(71) Applicant and
(72) Inventor: WHARTON, Robert, H. [US/US]; One Pine Knoll Road, Bedford, MA 01730 (US).

(74) Agents: GAGNEBIN, Charles, L., III et al.; Weingarten, Schurgin, Gagnebin & Lebovici, LLP, Ten Post Office Square, Boston, MA 02109 (US).

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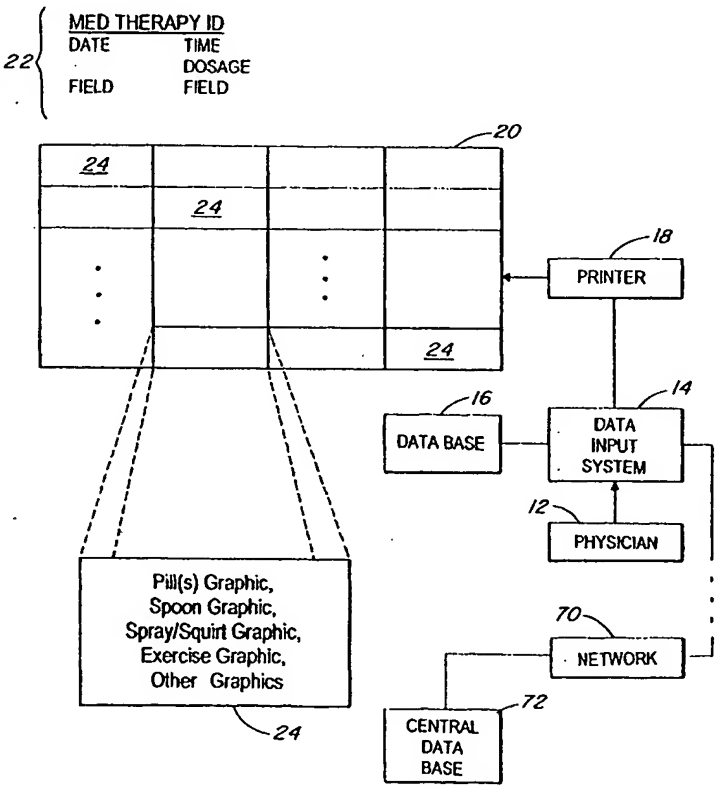
[Continued on next page]

(54) Title: PICTORIAL INTEGRATED PRESCRIPTION SYSTEM



(57) Abstract: A pictorial prescription software system to assist health care providers to prescribe medication accurately and reliably. A variety of database options (16) to ensure safe dosing, proper preparation and medication compatibility is provided. The software system will enhance patient safety through use of a computer-generated script (20) and a pictorial integrated prescription system (24). Patients will receive an illustrated medication guidance form (20) that displays graphically the medication to be taken as well as describing the dosage and frequency (28).

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PICTORIAL INTEGRATED PRESCRIPTION SYSTEM

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 60/312,934 filed on August 16, 2001, entitled PICTORIAL INTEGRATED PRESCRIPTION SYSTEM, the whole of which is hereby incorporated by reference herein.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

N/A

BACKGROUND OF THE INVENTION

Medication errors are an important problem for all individuals taking medications and for their providers. Missed doses, double doses, and dangerous combinations are believed to kill or injure 770,000 people a year. Hospital based studies of medication errors reveal an incidence of errors occurring at a rate of 5 per 100 medication orders. Errors in the community may have a similar (but more hidden) mortality rate, but a probable increased morbidity rate.

Recently, senators have called for one billion dollars to help hospitals and technology companies invest in devices to avoid deaths or injuries caused by errors. While no simple intervention has been demonstrated to significantly decrease morbidity and mortality, the use of computers to improve prescription reliability has been suggested. There have been no similar calls for enhanced community medication safety.

While medication errors affect all age groups, the young and elderly are likely to sustain a disproportionate number of preventable complications. For the young, errors may be secondary to inappropriate dosing, unanticipated side effects, errors in timing, omitted and extra doses and route or delivery errors. Dosing errors in children are caused by several factors. First, medication in children is frequently dosed according to the child's weight. When weights are not factored into a prescription dose, therefore, inadequate as well as excess doses can easily be given. While errors from excessive doses may be more apparent, errors from under dosing may be more insidious, resulting in ineffective treatment of infections and other common pediatric ailments. Children's doses of medication may also be prescribed in potential confusing regimes, such as a fraction of a pill or part of a dispensing device daily. For example, a child may require a quarter of a pill once or twice a day with a half pill before bed, or two cc's or half teaspoon twice daily.

Errors in the elderly are more complex - as well as more hidden - and are likely to be more severe. In addition to those listed above, the elderly are particularly susceptible to sedation and confusion. These two side effects, either separately or together, are frequently a critical factor in falls that result in fractures and head injuries. Fractured hips commonly lead to immobility and hospitalization, which can result in admission to a rehabilitation or convalescent facility or nursing home. Head injuries can lead to incapacitation and death.

In addition to children and the elderly, certain other populations may be more vulnerable to medication errors. These include people who are predominantly non-English speaking, people who are illiterate or are significantly learning disabled, people with vision problems, and people with other vulnerabilities.

Systems previously developed to reduce medication errors have generally been "reminder systems." These systems convey the supposition that it is the patient who is generally at fault for either forgetting to take his/her medication or for not taking their medication at the proper time. While people are clearly fallible in their medication taking habits, and therefore remedies for this problem are needed, correctable errors are also clearly related to factors described above.

Therefore, only a comprehensive system will be able to confront the morbidity and mortality of medication errors. First, a clear and legible computer-generated prescription, printed in a patient's primary language, is a critical necessity for safe prescribing. An integrated supportive prescribing system can also ensure safe and appropriate age dependent dosing, enhance awareness of potential age related complications, provide dosage alteration related to kidney or liver disease, and assure recognition of incompatible combinations of medication.

Second, the pictorial support system will enhance accurate dispensing of medication. Parents who give their children fractions of pills either on a regular basis or in an increasing or decreasing dose formulation may be uncertain about the amount of medication to be given. In addition, giving more than one medication may generate further difficulties. Parents would likely decrease their potential for errors by using a pictorial system. In this system the required dosage would be printed on a calendar to assist with safe dispensing. Increasing or decreasing amounts of medication would be clearly displayed as a dose of a fraction of a pill for example.

The pictorial system would also enhance accurate medication taking for individuals taking two or more medications daily. In these situations, especially when medications are prescribed for different times of the day, a picture system which clearly represents the shape and size of the medications would likely

decrease errors significantly not only for the patients themselves but in situations where caregivers are the dispensing agents. The pictorial representations could be readily displayed in convenient locations to serve as appropriate supports. Further, individuals could take these representations with them during times they travel.

BRIEF SUMMARY OF THE INVENTION

According to the invention a pictorial integrated software system provides graphic medication dosage instructions, reduces dispensing errors with clear and accurate computer written prescriptions, protects vulnerable populations such as children, the elderly, patients on multiple medications and individuals with chronic illness by ensuring appropriate dose, and enhance patient accuracy and compliance in medication taking through a pictorial prescription.

The system of the invention will assist individual providers, group providers, and HMO's with office record keeping, efficiency and general patient care, enhancing safe medical practice, and by reducing medication errors improve the health of their patients.

According to the invention the physician enters basic identifying data for attending doctor and patient demographics and drug and dosage. The system permits entry of dosage by time of day and date and then prints and/or displays a graphical presentation of drug icons in a quantity appropriate to each time of administration.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

These and other features of the invention are described below in conjunction with the Drawings of which:

Fig. 1 is a generalized view of a patient medication dosage administration chart;

Fig. 2 is a view of a typical patient administration chart completed with an exemplary medication load;

Fig. 3 is a typical entry form for physician information;

Fig. 4 is a typical information entry form for patient data;

Fig. 5 is a typical data entry form for drug identification and generalized prescription;

Fig. 6 is a detailed medication prescription data entry form;

Fig. 7 is an icon selection menu for selecting administration type;

Fig. 8 is a display of information assembled from Figs. 3-7;

Fig. 9 is a medication schedule allowing daily and hourly variation of dosage level for entered medication; and

Fig. 10 is a menu for selecting data entry forms for use in the invention showing data flow.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates a generalized form for practicing the invention. As shown there a physician 12 will input data into a system 14 with data typically stored in a database 16 or 72 for subsequent use, display or printing. That data is printed or displayed through a printer or other output device 18 creating a graphical presentation of medication dosage in a form typically represented by chart 20. The chart 20 contains a field 22 of basic identifying information which can include doctor and patient identifiers along with identification of the medication or therapy being scheduled. The chart 20 includes selected field 24 corresponding to a particular time of day, such as morning, evening, night. In each field 24 there is a iconographic presentation illustrating the particular medication by image which can include pills, spoons, spray or squirt applicators, dropper,

syringe as well as exercise or therapeutic body motions or other graphic icons. In the case of pills, the dosage can be illustrated in whole or fractions of a pill or combinations, spoons by spoon number or drops, in the case of a droplet applicator. Numeric indicator can also be used. The same would apply for squirting or spraying applicators and for repetition of particular exercises, typically showing a sequence of moves with a number of repetitions or duration information. With particular iconographic information can be stored in database 16 or 72 and retrieved under physician directive through the data input system 14, typically a computer terminal of a network 70.

Fig. 2 illustrates a sample completed form for a 7-day period and includes the data field 22 of demographic information, the data field 26 of general information for dosage or information seeking and the chart 20 showing pill icon 28 in a quantity reflecting the dosage to be administered over three periods of a each day for the 7-day period of time.

In practicing the invention doctors' offices are provided with software to enable them to print out instructions. Doctors could first hand write, key in, a prescription in the typical fashion. Then, or initially the physician or an office health care assistant would use the software system to print out the visual instruction. With this system the doctor's office would accomplish the following: a significant decrease in medication errors, create a date base for medications, doses and instructions for easy reuse and evidence of instructions, and save office time explaining medication regimen. Additionally, with a networkable system it would be possible via remote units to allow doctor use from different locations, home, hospital, golf course, etc., provide additional software that will help decrease errors, PDR, etc., store patients information for easy access, including allowing patients, password protected, access to new replacement

prescriptions. Additionally, pharmacies could have similar access.

The Pictorial Integrated Prescription System will have five sections. After the physician fills out the first few sections, he or she will have two buttons to choose from. The first button will initiate the printing of the prescription, which the physician will then sign by hand, and the second will initiate a new screen where the patient-specific graphical instructions can be entered and printed separately for the patient to take home for reference and use in taking the appropriate dosage at the appropriate time.

Section 1 - Physician Demographics

Fig. 3 shows an input form for doctor information. This section will have fields to identify the prescribing physician. Fields like Name, Institution, Address, Phone, and DEA No. These fields are either entered by hand, or if connected to a central database 72, a lookup can be done into an existing physician database in database 16 to pull in these fields automatically.

Section 2 - Patient Demographics

A further section shown in Fig. 4 has fields to identify the patient receiving the prescription. Fields may include Name, Address, Phone, Age, Weight, and Sex. These fields are either entered by hand or if connected to a central database 16, the patients medical record can be identified and the fields will all be filled automatically. Depending on the complexity of the system, a section could be added to list any medications the patient is currently taking and a section to list any known allergies.

Section 3 - Prescription Entry

Fig. 5 illustrates a form where the physician chooses the medication name and, in a separate free-text field 30, writes the pharmacy-specific prescription text. Once this section is filled out, the "Print Prescription" button can be pressed to generate a computer-generated prescription with all fields but "Signature" filled in. Once signed, this is handed to the patient to be delivered to their local pharmacy to be filled.

Section 4 - Schedule Parameters Selection

Fig. 5 illustrates the form for entry of scheduling data. In this section, the physician makes some preliminary choices about how the medication schedule will look. The first field 40 allows the physician to choose the medium the medication is delivered in. A drop-down menu, Fig. 7, lets the physician choose from many options. Choices may include Drops, Patch, Pills, Puffs, Tablespoons, Teaspoons, or Syringes. Similar exercise motions can be added. The choice dictates the type of graphic used on the actual entry screen and the printout given to the patient. Depending on this first choice, several more specific options may be offered, such as different shapes or colors of pills, syringe fill level, number of drops or pills, puffs, etc. The selected icon as shown in field 46 the "Starting Date" will default to present date, but can be easily changed to any date. The physician must also fill in the numeric "Frequency" per day and "Duration" fields 42 and 44, which dictate how many cells will appear in the actual medication schedule grid (See section 5). Once all these fields are filled in, pressing the "Enter Patient Instructions" button 48 will bring physicians to a new screen where they can highly customize the schedule in a graphical format. Modifications can be made down to the actual hours or fraction of a pill if necessary.

Fig. 8 illustrates the data thus far entered assembled in a combined form 50.

Section 5 - Graphical Medication Schedule Entry

Fig. 9 illustrates any entry form for customizing dosage on a daily and hourly basis. On this screen is a grid with a column 60, of dates down the left side and times of day in selection windows 62 across the top. Each cell 64 of the grid has several fields 66, 68 and 70, which vary depending on the delivery mechanism of the medication. For instance, a cell for a mediation delivered in a pill form would have a drop down menu allowing the physician to choose how many pills should be taken at that time. Once a choice has been made, the corresponding pill image(s) will appear beside, graphically confirming the physician's choice.

A choice of "1" in the pill window 66 would generate one complete pill image and a quarter of a pill image conveying that a pill should be broken into pieces. A choice of "4 drops" would generate four small images of a drop or possibly an image of a partially filled medicine dropper with a numeric. Other choices would generate other images. Some medication mediums might not lend themselves to an image, so a free-text field would be used instead.

The actual printout of the medication grid as shown in Fig. 2 will only differ slightly from the screen the physician sees. In place of the form elements used by the physician to choose the dose, it will instead print boxes the patient will check off when they take the medication. This will help the patient remember if they took their medication preventing accidental overdose. Alternative print format choices could be made, possibly a format that looks like a standard calendar.

Fig. 10 illustrates and overall computerized system for accessing various data entry forms for providing a complete patient medication administration selection and in graphical instruction form through a central data input system or on a network 70 with a central database 72. A core program 80 operates with a patient database 82 and collects select menu boxes such as box 84 to provide display and entry of basic patient information including not only that entered via Fig. 4 but also information on specific patient information such as age and medical condition such as pregnancy, renal disease, allergies or other potential incompatibility. A click box 86 allows entry of drug specific precautions such as side effects or the drug incompatibilities or inter-reactions and allergic responses as well as allowing retrieving from memory, if already there, such information.

A box 88 provides inputting specific precautions for a drug such as that related to age, dosage limits, illness concerns and status such as pregnancy concerns.

The system of the invention may also provide through click selection box such as box 90 default or click select prescription writing using a standard dose, if unnecessary to customize for a particular patient and/or their condition.

In the case where the physician is prescribing a new medication a click box 92 allows the entry to the forms presented and discussed above including, after basic demographic information entry, selection through click box 94 of dose and frequency information. In the case where the drug being prescribed is a renewal, a click box 96 may be provided with further processing selections for renewing the dose with our without changes through box 98 or commencing a gradual withdrawal of medication through box 100. A box 102 allows direct access without renewal request to change or generate a special dosage situation.

Once all data is assembled, or in fact even part way through the process, a click box 104 allows printing and/or display of the

completely assembled dosage instruction set including graphic display for checking and/or delivery to patient.

TABLE 1

DATABASE

Medication information
Calendar program
Pictures of medication
Generic and trade names
Precautions
Clock
Date and time
Word program
Graphics
Letter templates
Fax templates
Prescription templates
Calculator
Language
Labels
Address book

Table I shows typical elements of programming or data included in the database used with the invention. It includes medication information that indicates any side effects, incompatibilities and in a separate field below precautionary data. A calendar program drives the organizing of entered data into the formation for the chart to be displayed or printed. An Icon image memory shows pictorial versions of the medication to be administered or other therapies performed. A clock, date and time function allows the computation and display of selectable times for administration. A word processing program is for composing

instructions. A graphics generator allows the user to create pictographic representations not already in the database for user selection in writing the prescription. Fax and letter templates allow for the communication of charts electronically. Prescription templates allow simplified creation of conventional prescription scripts. A calculator function allows calculation of intervals and checking that dosages are not excessive. A language function allows use or output of information of different languages by translation functions. Labeling data allows output of forms for giving to the patient, adhering to the medication or otherwise and an address book keeps list of patients and physicians and other clinicians for quick retrieval.

The invention is to be limited only according to the following claims.

CLAIMS

What is claimed is:

1. A Process for generating an iconographic medication or therapy administration chart comprising the steps of:

generating a patient administration data base of information including at least patient identification, medication or therapy identification, and administration frequency and dosage at designated plural times over a course of treatment; and

organizing said information into a form that identifies administration at each designated time over said course of treatment with selected icons having dosage indicia and a pictorial feature identifying the medication or therapy.

2. The method of claim 1 wherein said generating step includes the step of displaying for user selection fields for information to be included in said database.

3. The method of claim 1 or 2 wherein said data base includes said icons and said generating step includes the step of displaying a representation of said icons for user selection to become part of said information in said data base.

4. The method of claim 1, 2, or 3 wherein said displaying step displays icons of one or more or a pill, patch, dropper, syringe, exercise, squirt or spray applicator.

5. The method of claim 1, 2, 3, or 4 wherein said dosage indicia includes repetitions of all or part of said icons.

6. The method of claim 1, 2, 3, 4 or 5 wherein said generating step includes the step of generating medication or therapy prescriber identification to be included in said information.

7. The method of claim 1, 2, 3, 4, 5 or 6 including the step of displaying and or printing a chart from said information in said form and having a grid of administration times organized by date and time with each grid having said icons with dosage indicia.

8. The method of claim 1, 2, 3, 4, 5, 6 or 7 including step of performing said generating and organizing steps at a distance through a network.

9. The method of claim 1, 2, 3, 4, 5, 6, 7 or 8 including the step of translating said information between languages.

10. The method of claim 1, 2, 3, 4, 5, 6, 7, 8 or 9 including the steps of checking for patient condition or drug compatibility with said medication or therapy.

11. Repeating the method of claim 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 as a renewal of said medication or therapy.

12. Modifying the results of practicing the method of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 11 for purposes of patient withdrawal from said medication or therapy.

13. A chart created by the method of claims 1, 2, 3, 4, 5, 6, 7 or 8.

14. A system for performing the method of claim 1, 2, 3, 4, 5, 6, 7 or 8 comprising:

a database generating unit having a user input terminal;

a mass storage unit for said database;

a display device including a screen or a printer for displaying said information in a chart form.

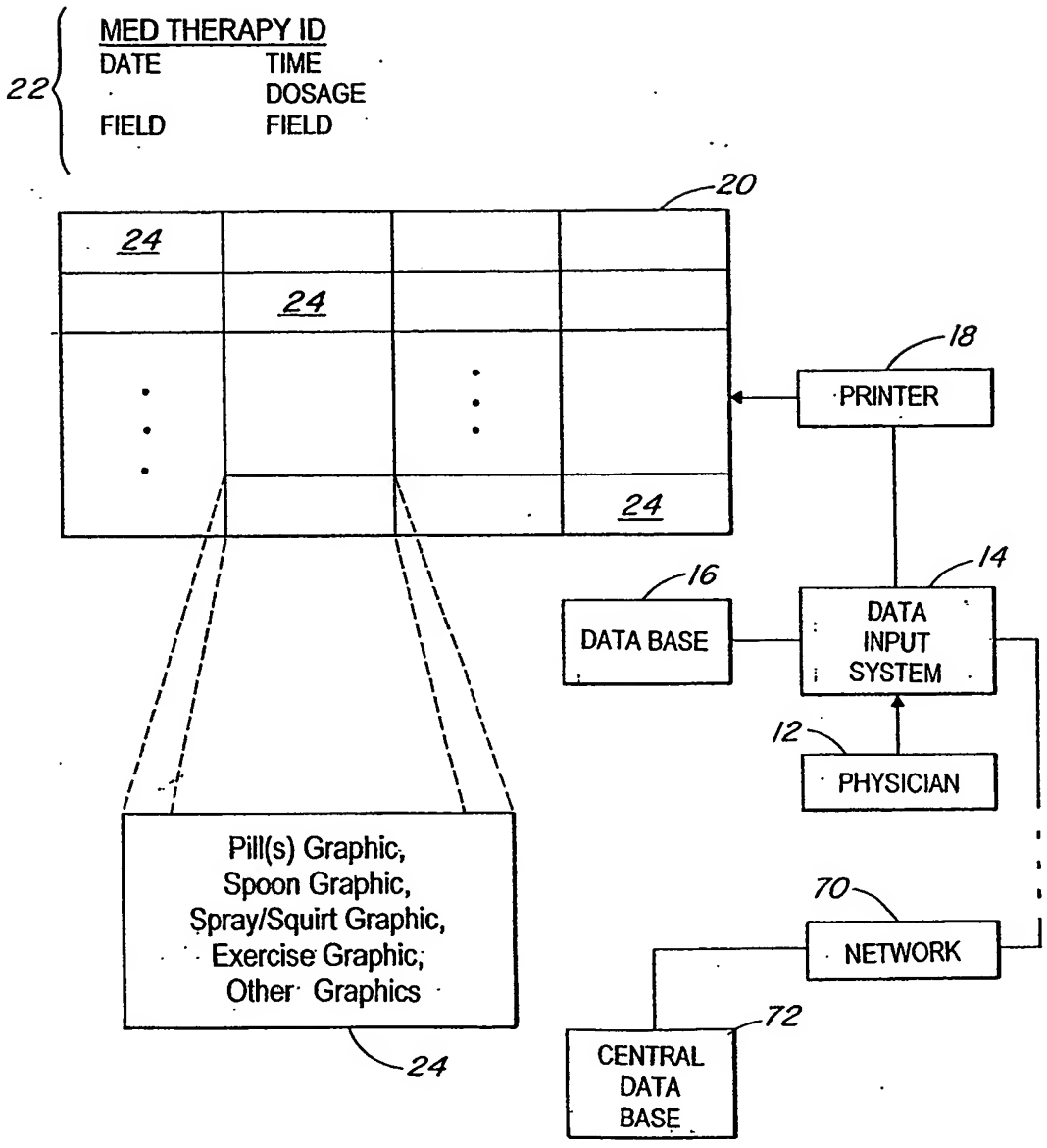
MED THERAPY ID
DATE
FIELD
TIME
DOSAGE
FIELD
22
20
24
24
24
18
PRINTER
16
DATA BASE
14
DATA INPUT SYSTEM
12
PHYSICIAN
Pill(s) Graphic,
Spoon Graphic,
Spray/Squirt Graphic,
Exercise Graphic;
Other Graphics
24
70
NETWORK
72
CENTRAL DATA BASE

FIG. 1

Focus

22

Patient Name:	Jane Doe	Date:	3/28/2001
Physician Name:	Dr. Robert Wharton	Weight:	45 Kg
Medication:	Acetaminophen	Age:	10

Instructions:

Please follow these instructions carefully. Please call the office at 617-321-4567 if you have any questions. This is just more text... This is another line. This is the last line. 26

20

Medication Schedule	Morning	Afternoon	Evening
Sunday, April 29, 2001			
Monday, April 30, 2001	28		
Tuesday, May 1, 2001			
Wednesday, May 2, 2001			
Thursday, May 3, 2001	28	28	28
Friday, May 4, 2001			
Saturday, May 5, 2001			

FIG. 2

Physician Name:		Date:	
Institution:		Phone:	
Address:		DEA No.:	

FIG. 3

Patient Name:	Pat Patient	Weight:	45 Kg.
Patient Address:	1 Main Street, Smallville	Age:	21
Other Medication:		Sex:	F

FIG. 4

Prescribed Medication:

Acetaminophen

Prescription

300 mg three times a day for 7 days

30

Print Prescription

FIG. 5

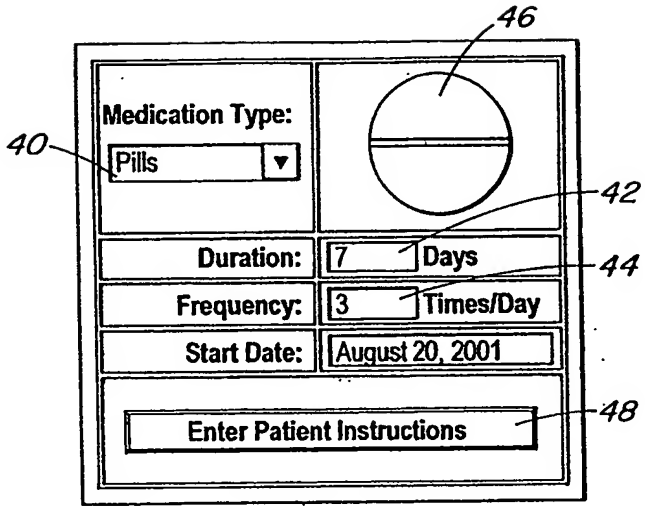
46
Medication Type:
40
Pills
42
Duration:
7
Days
44
Frequency:
3
Times/Day
Start Date:
August 20, 2001
48
Enter Patient Instructions

FIG. 6

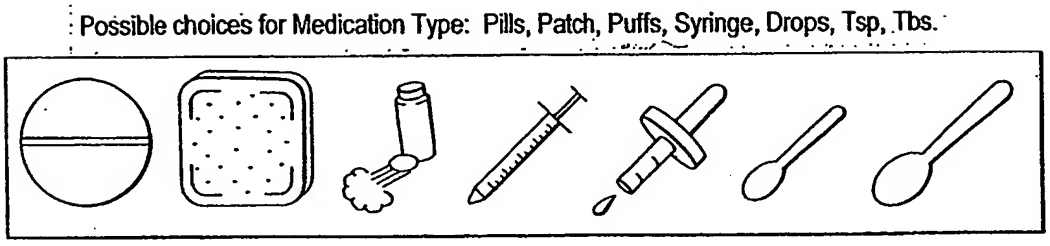
Possible choices for Medication Type: Pills, Patch, Puffs, Syringe, Drops, Tsp, Tbs.

FIG. 7

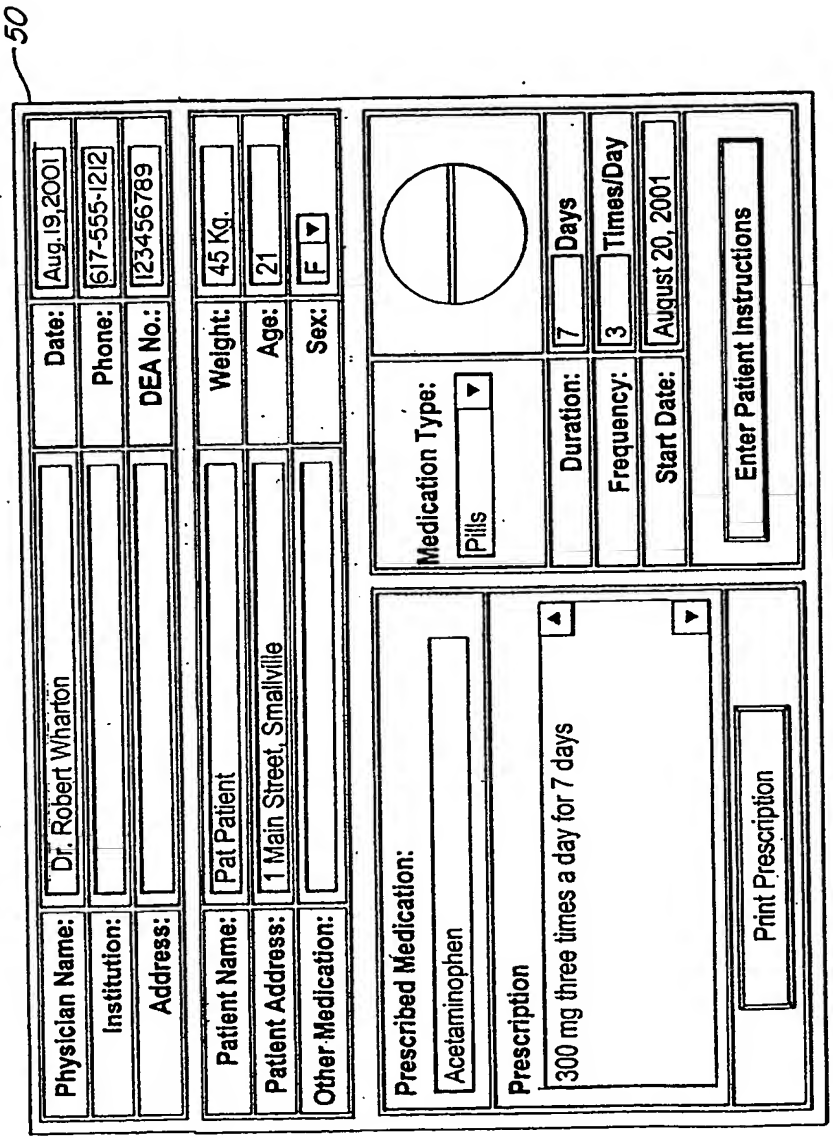
50
Physician Name:
Dr. Robert Wharton
Institution:
Address:
Date:
Aug.19,2001
Phone:
617-555-1212
DEA No.:
123456789
Patient Name:
Pat Patient
Patient Address:
1 Main Street, Smallville
Other Medication:
Weight:
45 Kg.
Age:
21
Sex:
F
Prescribed Medication:
Acetaminophen
Prescription
300 mg three times a day for 7 days
Print Prescription
Medication Type:
Pills
Duration:
7
Days
Frequency:
3
Times/Day
Start Date:
August 20, 2001
Enter Patient Instructions

FIG. 8

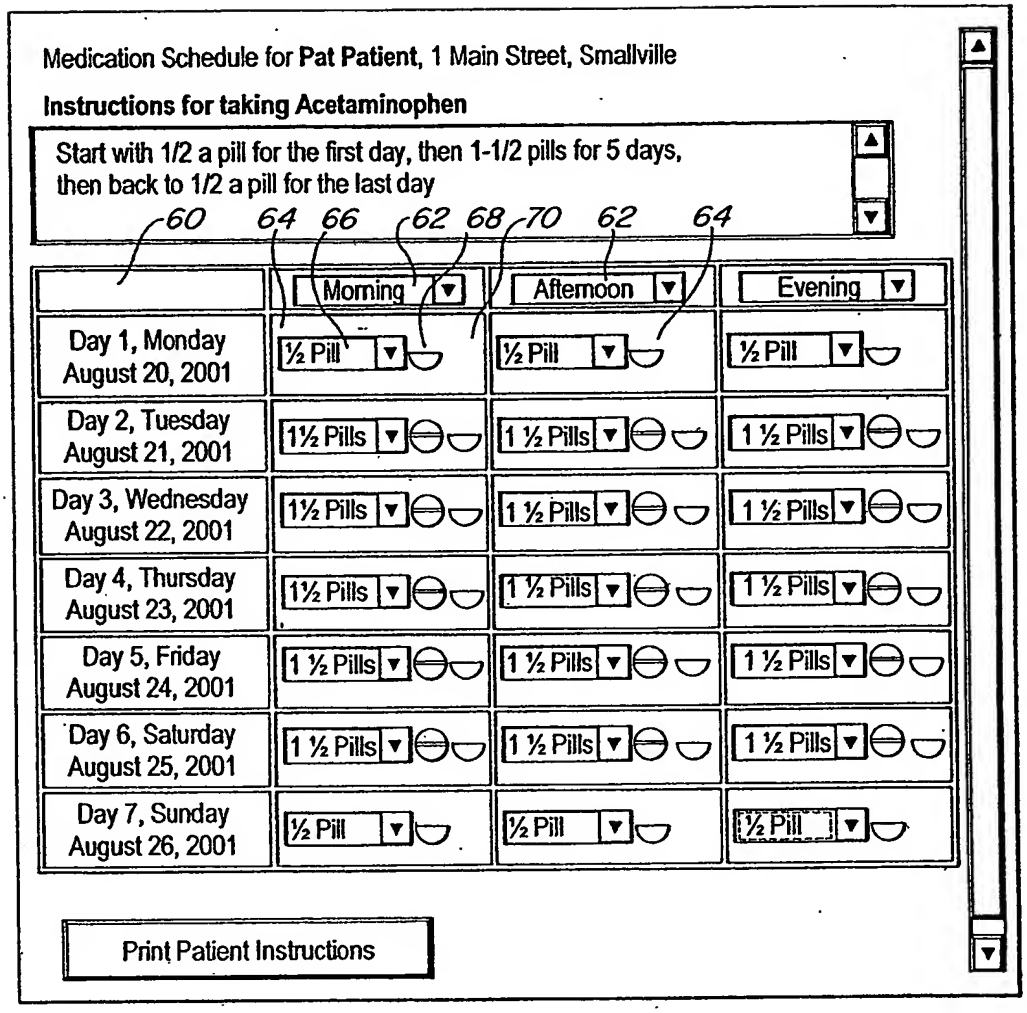
Medication Schedule for Pat Patient, 1 Main Street, Smallville
Instructions for taking Acetaminophen
Start with 1/2 a pill for the first day, then 1-1/2 pills for 5 days, then back to 1/2 a pill for the last day
60
64
66
62
68
70
62
64
Morning
Afternoon
Evening
Day 1, Monday August 20, 2001
½ Pill
Day 2, Tuesday August 21, 2001
1½ Pills
1 ½ Pills
Day 3, Wednesday August 22, 2001
Day 4, Thursday August 23, 2001
Day 5, Friday August 24, 2001
Day 6, Saturday August 25, 2001
Day 7, Sunday August 26, 2001
Print Patient Instructions

FIG. 9

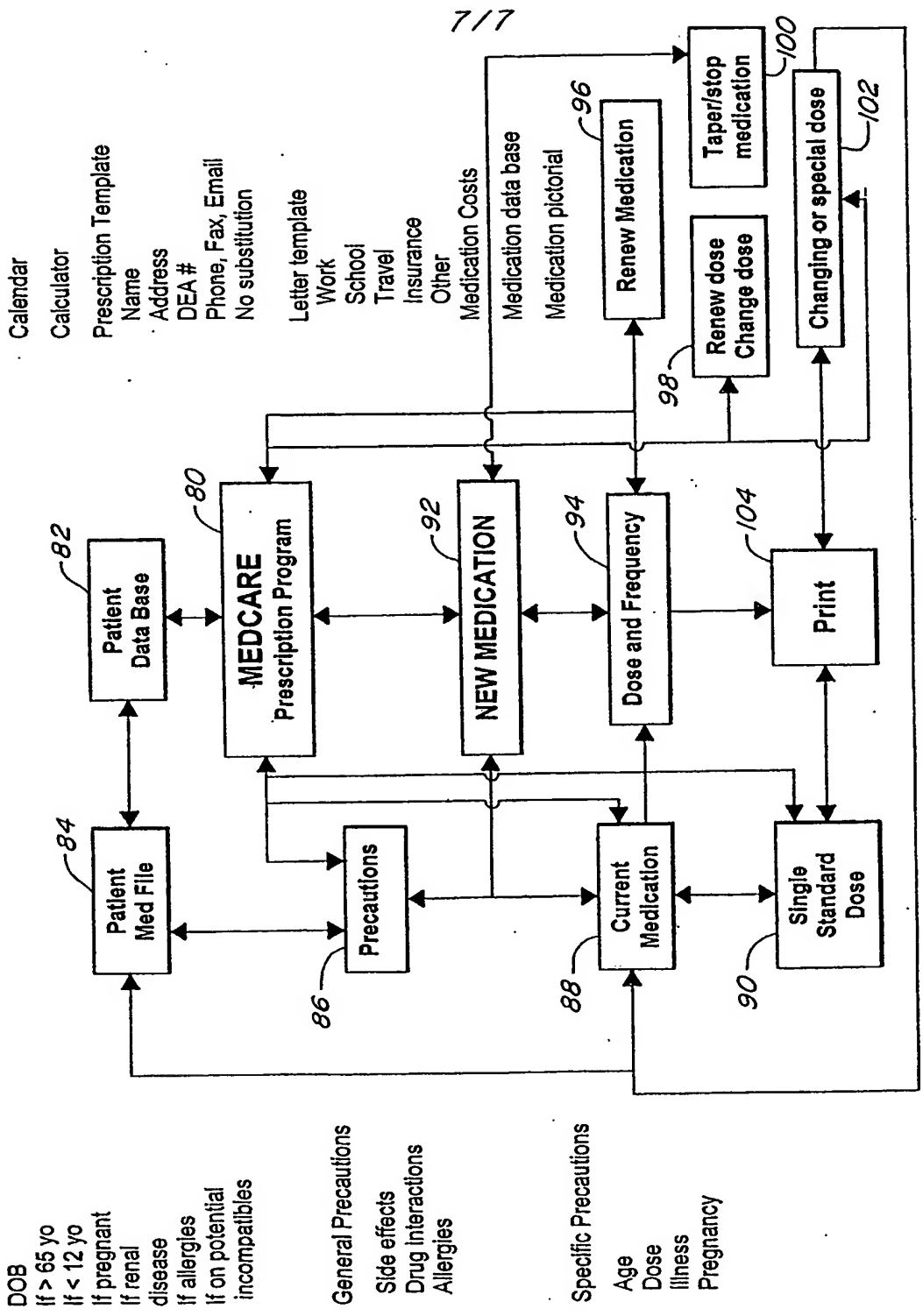
717
Calendar
Calculator
Prescription Template
Name
Address
DEA #
Phone, Fax, Email
No substitution
Letter template
Work
School
Travel
Insurance
Other
Medication Costs
Medication data base
Medication pictorial
Renew Medication
Taper/stop medication
Renew dose
Change dose
Changing or special dose
Patient Data Base
MEDCARE
Prescription Program
NEW MEDICATION
Dose and Frequency
Print
Patient Med File
Precautions
Current Medication
Single Standard Dose
82
80
92
94
104
96
100
98
102
84
86
88
90
DOB
If > 65 yo
If < 12 yo
If pregnant
If renal disease
If allergies
If on potential incompatibles
General Precautions
Side effects
Drug Interactions
Allergies
Specific Precautions
Age
Dose
Illness
Pregnancy

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/26293

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G06F 17/60
US CL : 705/3

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 705/3; 705/2; 705/4; 600/300, 709/202

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,960,403 A (BROWN) 28 September 1999 (28.09.1999), abstract, column 1, lines 12-21, Figure 2, column 9, lines 31-48.	1-14
Y	US 6,081,786 A (BARRY) 27 June 2000 (27.06.2000), abstract, column 2, lines 20-64, Figs. 5-7, Table 2.	1-14
Y	US 5,845,255 A (MAYAUD) 01 December 1998 (01.12.1998), abstract, column 1, lines 7-18; column 4, lines 22-65; column 31, lines 19-49.	1-14
Y	US 5,899,855 A (BROWN) 04 May 1999 (04.05.1999) abstract, column 9, lines 30-45.	1-14
A	US 6,067,523 A (BAIR et al) 23 May 2000 (23.05.2000), column 2, lines 41-65, column 3, lines 1-11, Figs. 5, 9, 10.	1-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Joseph Thomas Telephone No. (703) 308-1113

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Continuation of B. FIELDS SEARCHED Item 3:
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